510(k) SUMMARY
Gemini 220 XP Lithotripter

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier MedTech America
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Kennesaw, GA 30144

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Date Prepared: September 19, 2013

Contact Person: John Hoffer
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Name of Device and Name/Address of Sponsor
Gemini 220 XP
1155 Roberts Blvd.
Kennesaw, GA 30144

SEP 2 3 2013

Common or Usual Name
Shock Wave Lithotripter

Classification Name
According to 21 C.F.R. § 876.5990, FDA has classified extracorporeal shock wave lithotripters as Class II devices with special controls. The Product Code for these lithotripters is LNS.

Predicate Devices
Dornier Gemini Lithotripter (K121656)
Dornier Doli S XP Lithotripter (K011873)

Purpose of the Special 510(k) Notice
The Gemini 220 XP is a modification to Dornier's Gemini Lithotripter (K121656).

Intended Use
The Gemini 220 XP is indicated for the fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones.

Device Description
The Gemini 220 XP is a modular urological work station designed for extracorporeal shock wave lithotripsy ("ESWL") and for diagnostic and therapeutic procedures usual in Urology.

The Gemini 220 XP is composed of the following modules:

- Basic Unit with integrated X-ray C-arm and Therapy Arm for Shockwave Treatment;
- Patient Table;
- Control Desk – User Interface; and

The basic unit contains the power supplies, control unit, power electronics for motor drives, components for shockwave generation, and an integrated Therapy C-arm and an X-Ray C-Arm. The housing can be positioned with its back close to the room wall and has wide side doors for easy service.

The therapy and X-Ray C-arm house the shock wave source ("EMSE") and the complete X-ray unit. The X-ray unit consists of the X-ray generator, the X-ray tube, an image receptor system, and a high resolution imaging chain. This provides the imaging to perform the procedures. The C-arms allow for a wide range of movement to facilitate performing urological procedures.

The shock wave circuit supplies the shock wave energy needed for the treatment of kidney stones.

The Gemini 220 XP's urological patient table provides longitudinal, lateral and vertical travel range to allow easy positioning of the stone in the shock wave focus for lithotripsy and urological procedures. It is the same as in the predicate device.

The image processing system with DICOM 3 capability supports PACS connection and offers complete X-ray control and image handling.

Performance Data

The company has complied with all of the requirements described in FDA's *Guidance for the Content of Premarket Notifications (510k's) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.*

The device is in compliance with the following standards:

• IEC 60601-1:2007	Electrical safety of medical devices
• IEC60601-1-2:2007	Electromagnetic compatibility
• IEC 60601-1-3:2008	Radiation protection
• IEC 60601-1-6:2008	Usability
• IEC 60601-2-7	Safety of high-voltage generators of diagnostic X-ray generator
• IEC 60601-2-28	Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
• IEC 60601-2-36:1997	Extracorporeally induced Lithotripsy
• IEC 60601-2-32:1995	Safety of X-ray equipment
• ISO 13485:2003+AC:2007	Quality management system
• IEC 61846	Ultrasonics – Pressure pulse lithotripters characteristic of fields

In summary, during the design and verification testing, the acoustic output of the EMSE, the electrical safety of the system and any electromagnetic compatibility issues were fully addressed by demonstrating compliance with the appropriate standards. There were no unanticipated risks identified. Lastly, the device manual was reviewed and approved as part of the design control process. It contains all necessary warnings, cautions and instructions to mitigate potential injuries.

Substantial Equivalence

The Gemini 220 XP has similar technological characteristics as the predicate FDA-cleared Gemini Lithotripter (K121656), to which it is a modification. The Gemini 220 XP and the Gemini are extracorporeal shock wave lithotripters used for fragmentation of urinary tract stones, i.e., renal calyceal stones, renal pelvic stones, and upper ureteral stones. The technology to perform this function involves use of an electromagnetic shock wave emitter ("EMSE"). In the case of the subject device, the identical shock wave source is used as in the cleared predicate product, the Doli S XP (K011183). The other primary elements of the Gemini 220 XP, i.e., the patient table and the X-ray unit, are the same to that of the Gemini (K121656). They perform the same function and operate in the same manner during the procedures involved in the fragmenting of urological stones.

From a clinical perspective and comparing design specifications, the Gemini 220 XP and the predicate devices are substantially equivalent and have the same intended use.

Dornier Medical Systems, Inc. believes the minor differences do not raise any concerns regarding the overall safety or effectiveness. Thus, the Gemini 220 XP is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 23, 2013

Dornier MedTech America, Inc.
% John S. Hoffer
VP Quality, Regulatory, Clinical
1155 Roberts Blvd., Suite 100
Kennesaw, GA 30144

Re: K132672
Trade/Device Name: Gemini 220 XP
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: August 26, 2013
Received: August 27, 2013

Dear John S. Hoffer,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132672

Device Name: Gemini 220 XP

Indications for Use:

The Gemini 220 XP is indicated for the fragmentation of urinary tract stones, i.e. renal calyceal stones, renal pelvic stones, and upper ureteral stones.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S